

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following reasons.

I. Status of the Claims

Upon entry of this amendment, claims 38 and 54-61 are pending. Claims 1-37 and 40-52 are withdrawn from consideration. Claim 53 was previously cancelled. Claim 39 is cancelled. Claim 38 is amended currently. Claims 54-61 are newly presented. A detailed listing is presented, with an appropriate defined status identifier, of all claims that are or were in the application, irrespective of whether the claim(s) remain under examination in the application.

II. Rejection of claims 38 and 39 under 35 U.S.C. § 112, second paragraph

Claims 38 and 39 are rejected for alleged indefiniteness. Office Action at page 3. Claim 39 is canceled. The examiner alleges that the phrase “capable of” is not a limitation “in any patentable sense.” *Id.* Claim 38 is amended to delete the recitation “capable of.” The examiner also urges that “substantially incapable” is vague and indefinite. *Id.* Claim 38 is amended to delete “substantially.” Finally, the examiner alleges that the phrase “together with one or more pharmaceutically acceptable carriers and/or diluents” renders claim 38 vague and indefinite. *Id.* Claims 38 is amended to delete the recitation in question.

The examiner also alleges that the phrase “a microorganism GPI inositolglycan” and the term “molecule” are vague and indefinite. More particularly, the examiner alleges that these claims are overly broad. Applicant respectfully disagrees. The second paragraph of section 112 requires only that the claims reasonably apprise those skilled in the art of the scope of the claimed invention. *See e.g. Miles Lab, Inc. v. Shandon, Inc.*, 27 U.S.P.Q.2d 1123 (Fed. Cir. 1993), *cert denied*, 510 U.S. 1100 (1994), *see generally* M.P.E.P. § 2173.02. Furthermore, it is the examiner who has the initial burden of demonstrating that one of skill in the art would not appreciate the metes and bounds of the claimed subject matter. M.P.E.P. § 706.03.

The examiner fails to meet the burden of demonstrating that one of skill in the art would not appreciate the metes and bounds of the claimed subject matter. One of skill in the art would clearly understand the term "a microorganism inositolglycan." Moreover, there is ample definition and description for this term throughout the instant specification to properly inform a skilled artisan. For example, the specification states:

The term "micro-organism" should be understood in its broadest sense and includes, for example, the parasitic and fungal taxa *Plasmodium*, *Trypanosoma*, *Leishmania*, *Toxoplasma* and *Candida*. "Micro-organism" should also be understood to extend to molecules which are secreted by or shed from the subject organism. This would include for example, toxin molecules or molecules which are cleared from the surface of the micro-organism. Preferably, the GPI inositolglycan domain suitable for use in the present invention is a parasite GPI inositolglycan domain and even more preferably a *Plasmodium* GPI inositolglycan domain.

Page 16, lines 10-17.

Similarly, the term "molecule" as used in claim 38 would be readily understood by a skilled artisan and would reasonably apprise a skilled artisan of the scope of the claims. Webster's New Collegiate Dictionary defines "molecule" as "the smallest particle of a substance that retains the properties of the substance and is composed of one or more atoms." WEBSTER'S NEW COLLEGIATE DICTIONARY, G. & C. Merriam Co (Springfield, MA) 1976, at page 741 (copy enclosed). Throughout the specification there is further clarification of the term "molecule." For example, the specification states:

The term "GPI inositolglycan" is used interchangeably with terms such as but not limited to "inositolglycan" (IG), "inositophosphoglycan" (IPG), "phosphoinositolglycan" (PIG), "phosphooligosaccharide" (POS) and the molecules described by these terms should be understood as "GPI inositolglycan" molecules.

Page 13, lines 23-26. The specification further states:

Preferably the molecule is a portion of GPI which comprises the inositolglycan domain or derivative or equivalent thereof

but substantially does not contain a portion capable of inducing an immune response directed to a lipidic domain of said GPI.

Page 14, lines 4-6.

While Applicant submits that the scope of the claims would be understood by the skilled artisan, certain claim terms have been amended to expedite prosecution. Claim 38 is amended to delete reference to the “molecule” and to specify that the molecule is the inositolglycan domain portion of GPI.

The examiner also alleges that the term “insufficient” renders claim 39 vague and indefinite. Although claim 39 is canceled, the term “insufficient” is recited in new claim 54. Here again, the examiner fails to meet the burden of demonstrating that one of skill in the art would not appreciate the metes and bounds of the claimed subject matter. It would be clear to the person of skill in the art what is meant by this term, that is, that there is insufficient lipidic domain present to induce an immune response to the lipidic domain. In this regard, it would be a matter of routine procedure for the person of skill in the art to determine how much of the lipid domain need be removed in order to achieve this objective. Applicants maintain that the claim would reasonably apprise those skilled in the art of the scope of the claimed invention.

Withdrawal of the rejection of amended claim 38 is respectfully requested.

III. Rejection of claim 38 under U.S.C. § 102(b)

Claim 38 is rejected under 35 U.S.C. § 102(b) as anticipated by Tachado *et al.*, *J. Immunol.* 156:1897 (1996), or Tachado *et al.*, *Biochem Biophys Res Commun.* 205:984-91 (1994). The Tachado references are cited as disclosing GPI and anti-GPI monoclonal antibodies.

The present invention is predicated, *inter alia*, on the determination that GPI or a GPI-derived glycan or inositolglycan can be used as a vaccine or a vaccine target. Prior to the present invention, the development of vaccines against parasites focused on the use of proteins to elicit an immune response, without consideration of the sugar component.

Applicant respectfully submits that the Tachado references cited do not disclose a GPI molecule that induces an immune response directed to a microorganism GPI inositolglycan domain, but that does not induce an immune response to a lipidic domain of the GPI, as recited in amended claim 38. Applicants respectfully request withdrawal of this rejection.

Claims 38 and 39 are rejected as anticipated by Tachado *et al.*, *Proc. Nat'l Acad. Sci. U. S. A.* 94: 4022 (1997), Schofield *et al.*, *J. Immunology*, 156: 1886 (1996), or Richardson *et al.*, *Insect Molecular Biology* 1: 139 (1993). Claim 39 is canceled and, thus, the rejection of that claim is moot. The examiner alleges that Tachado *et al.* (1997), Schofield *et al.*, and Richardson *et al.* anticipate the present invention.

Tachado *et al.* (1997) demonstrates that GPIs activate host macrophages and studies the structure/activity relationship determine the mechanism of action of this molecule. Tachado *et al.* (1997) does not teach the concept of a vaccine directed towards protozoal infections by a whole GPI. Moreover, Tachado *et al.* (1997) also does not teach a modified GPI molecule or derivative thereof, which induces an immune response directed to a microorganism GPI inositolglycan domain, but that does not induce an immune response to a lipidic domain of the GPI, as recited in amended claim 38.

Similarly, the Tachado *et al.* references of 1994 and 1996 do not teach a GPI molecule or derivative thereof, which induces an immune response directed to a microorganism GPI inositolglycan domain, but that does not induce an immune response to a lipidic domain of the GPI, as recited in amended claim 38.

Schofield *et al.* (1996) expand upon the idea that GPIs may regulate host cell function. Yet Schofield *et al.* does not teach a GPI molecule or derivative thereof, which induces an immune response directed to a microorganism GPI inositolglycan domain, but that does not induce an immune response to a lipidic domain of the GPI, as recited in amended claim 38.

Richardson *et al.* (1993) discusses the production of a vaccine against ticks. The target antigen in the reference is a protein which, under natural conditions, has a GPI anchor. Richardson *et al.* explores the signals which result in a GPI anchorage and, therefore, assays various constructs in an expression system. The goal of the study in Richardson *et al.* is a

molecule lacking the GPI anchor. Richardson *et al.* asserts that the protein is the desirable component of their vaccine. Accordingly, the reference describes a method of producing the target protein lacking a GPI using expression systems to remove the GPI. Richardson *et al.* states, “the GPI anchor is not essential for the expression of the protective immunological response...” (Richardson *et al.* at page 145, left column, lines 39-40) and “. . . the production of BM86trun (*i.e.* lacking GPI) as a secreted form of BM86 allows efficient recovery and purification of relatively large quantities of this recombinant protein.” Richardson *et al.* at page 145, left column, at lines 32-35 (parenthetical added). Moreover, Richardson *et al.* note:

“recombinant BM86 was originally expressed as an inclusion body in *E. coli* . . . this form. . . did induce a strong immunological response This result rules out a major involvement of carbohydrate residues on BM86 in the protective response as recombinant proteins produced in bacteria are not glycosylated.”

Richardson *et al.* at page 145, left column, first full paragraph. Therefore, clearly Richardson *et al.* does not teach a GPI glycan or inositolglycan molecule that induces an immune response directed to a microorganism GPI inositolglycan domain, but that does not induce an immune response to a lipidic domain of the GPI, as recited in amended claim 38.

Applicant respectfully requests withdrawal of the rejection.

Applicant believes that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By S. A. Bent

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

